



ChoiceSpine
Propelling Spinal Surgery

Stealth™ Cervical Spacer System
Instruction for Use



General Description:

The STEALTH Cervical Spacer System consists of intervertebral body fusion devices (“interbody spacers”) comprised of polyetheretherketone (PEEK-OPTIMA® polymer, Invivio®) with tantalum markers (ASTM F2026 and ASTM F560, respectively). The spacers have a basic oval shape that coincides with the shape of vertebral bodies, a hollow center for placement of bone graft, and angled ridges, or “teeth,” on both the superior and inferior surfaces for resisting migration. They are available in an assortment of heights and in multiple angles of lordosis to accommodate different anatomic requirements.

Indications for Use:

The STEALTH Cervical Spacer System is intended for anterior cervical spine intervertebral body fusion at one level from the C2-C3 disc space to the C7-T1 disc for the treatment of degenerative disc disease (DDD) in skeletally mature patients who have had six (6) weeks of non-operative treatment. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is to be used with autogenous bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and supplemental fixation to facilitate fusion.

Contraindications:

Contraindications for the STEALTH Cervical Spacer System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Conditions, such as morbid obesity, which may put excessive stress on the bone and implants
3. Severe osteopenia or osteoporosis may prevent adequate fixation
4. Suspected or documented metal allergy
5. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions
6. Pregnancy

Warnings:

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. A satisfactory outcome is enhanced by the selection of the appropriate device size and angle.
3. The Stealth Cervical Spacer System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Stealth Cervical Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions:

1. The STEALTH Cervical Spacer System should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques as this is a technically demanding procedure.
2. The spacers should not be reused even if they appear in a perfect state. Any spacer that has been used, twisted, bent, implanted and then removed, even if it appears intact, must be discarded.
3. The STEALTH Cervical Spacer System is used to augment the development of a spinal fusion by providing temporary stabilization. The device (spacer) is not intended to be the sole means of spinal support. Supplemental internal fixation must be used. Bone grafting must be part of the spinal fusion procedure. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant’s longevity.
4. Refrain from handling the STEALTH Cervical Spacers as much as possible before implantation, and always handle it with the utmost care. STEALTH Cervical Spacers (in their original packaging) must be stored with care in a clean and dry place away from radiation or extreme temperatures. Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.

Preoperative:

1. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the device and the potential adverse effects of the surgery.
2. Only patients that meet the criteria described in the indications should be selected.
3. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery.

Intraoperative:

1. The surgeon must be fully conversant with all aspects of the surgical technique.
2. Proper function of the surgical instruments specific to the STEALTH Cervical Spacer System should be verified prior to every surgical procedure.
3. The appropriate type and size of implant for the patient and the positioning of the implant are important.

Postoperative:

1. Patients must be informed of the precautions to be taken in their everyday life to enhance a maximum implant service life.
2. Regular post-operative follow-up is recommended to detect early signs of implant failure and consider necessary action.

Potential Complications and Adverse Effects:

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

1. Early or late loosening of the components

2. Disassembly, bending or breakage of any or all of the components
3. Foreign body (allergic) reaction to the implants
4. Infection
5. Loss of neurological function, including paralysis, spinal cord impingement or damage
6. Dural tears, CSF leak or fistula or meningitis
7. Bone graft donor complications, including pain, fracture or wound healing problems
8. Vascular damage resulting in excessive bleeding and malpositioned devices adjacent to large vessels could cause vessel erosion and catastrophic bleeding.
9. Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise
10. Possible local or systemic adverse reactions from potential long-term degradation of the polymer or mechanical grinding causing wear debris
11. Bone loss due to resorption or stress shielding
12. Pseudoarthrosis
13. Death

Additional surgery may be necessary to correct some of these potential adverse effects.

How Supplied:

 The STEALTH Cervical Spacer System devices are provided non-sterile and must be sterilized prior to use. Implants are intended for single use only. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:

All instruments and implants must first be cleaned using methods recommended in this document or established hospital methods before sterilization and introduction into a sterile surgical field.

Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using methods recommended in this document or established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. These devices are packaged in a convenience caddy/case, all devices must be removed from the case and inspected and cleaned via one of the appropriate methods below.

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

Recommended Cleaning:

The terms “Steris 444”, “Enzol®” and “Prolystica®” are tradenames of ultrasonic equipment and detergents utilized in the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer’s instructions and labeling.

Automated Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High.

| Phase | Time (min) | Temperature | Detergent |
|-------------|------------|----------------|---|
| Pre-Wash 1 | 1:00 | Cold tap water | N/A |
| Enzyme Wash | 1:00 | Hot tap water | Enzol® at 1oz per 1 gal water |
| Wash 1 | 2:00 | 60°C | Prolystica® 2x Conc. Neutral at 1/8 oz per 1 gal water |
| Rinse 1 | 1:00 | Hot tap water | N/A |
| Drying | 7:00 | 115°C | N/A |

4. Remove instruments and inspect for soil, repeat cleaning if necessary.

Mechanical Cleaning (Ultrasonic):

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary.

Manual Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.

6. Remove instrument(s) from detergent & thoroughly rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth & filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

Care and Handling:

- All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.
- Refer to ASTM standard F1744-96, “Standard Guide for Care and Handling of Stainless Steel Surgical Instruments” for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities, DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Inspection:

The implants should be inspected after processing, prior to sterilization. Any implant with damage, corrosion, discoloration, scratches, residue, or debris should be discarded.

Sterilization:

The STEALTH Cervical Spacer System instruments are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments are recommended to be steam sterilized by the hospital using the following process parameters (Alternative methods or cycles may be used, but should be validated according to hospital practices and procedures).

Steam Sterilizer Type: Pre-Vacuum
Temperature: 132°C
Duration: 4 minutes
Drying Time: 40 minutes

All devices are to be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature).

Alternative sterilization methods or cycles may be used but should be validated according to hospital practices and procedures.

Single Use Only

Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Storage and Handling:

Implants should be stored in the implant sterilization case in clean, dry, well-ventilated conditions away from floors, ceilings, and outside walls. Store and transport sterile implant in such a way as to maintain sterility and functional integrity. Do not use implants if the sterilization wrap is opened, damaged or wet. Implants should remain covered until needed to avoid contamination. Only those to be implanted should be handled.

Limitations and Restrictions:

Repeated sterilization according to these instructions has a minimal effect on ChoiceSpine devices.

Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved.

These instructions have been validated as being capable of sterilizing these ChoiceSpine implants.

Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Patient Education:

It is essential to provide preoperative instructions to the patient. S/he should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Device Retrieval Efforts:

Should it become necessary to remove any or all of the STEALTH Cervical Spacer System components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

Surgical Technique Guide:

The STEALTH Cervical Spacer System Surgical Technique Guide is available by contacting ChoiceSpine Customer Service.

Caution:

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Information:

See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

For product complaints please contact:

ChoiceSpine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045

For additional product information please contact:

ChoiceSpine, LLC
Customer Service Department
400 Erin Drive

Symbol Legend:

| Symbol | Definition |
|--|---|
|  | Do not reuse |
|  | Caution, consult instructions for use for warnings and precautions |
|  | Consult instructions for use |
|  | Do not use if package is damaged |
|  | Lot number |
|  | Reference number |
|  | Serial Number |
|  | Sterilized by irradiation |
|  | Use by |
|  | Manufacturer |
|  | Date of Manufacture |
|  | Federal law (USA) restricts this device to sale by or on the order of a physician |
|  | Non-Sterile |
|  | European Medical Devices |
|  | Authorized representative in the European Community |